AUG 0 8 2009

3. 510(k) Summary of Safety and Effectiveness

Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Sally Foust Regulatory Affairs Project Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1251 Fax: 239/598.5508 Email: sfoust@arthrex.com
Trade Name	Arthrex Dual Wave Arthroscopy Fluid Management Device
Common Name	Pump
Product Code –Name –Reference	HRX – Arthroscope - CFR 888.1111
Predicate Device	Arthrex Continuous Wave Arthroscopy Pump, K024291 FMS DUO, K954465
Device Description and Intended Use	The Arthrex Dual Wave Arthroscopy Fluid Management Device is a roller, peristaltic, arthroscopic pump designed with a universal input grade switching power supply. The Arthrex Dual Wave Arthroscopy Fluid Management Device senses the connection and use of the Arthrex Shaver Adapteur System (K932699) and provides an outflow function to support the same. Arthrex Dual Wave Arthroscopy Fluid Management Device is intended to provide consistent, non-pulsing control of intra-articular irrigation and distention pressuring during all phases of arthroscopic surgery.
Substantial Equivalence Summary	The Arthrex Dual Wave Arthroscopy Fluid Management Device is substantially equivalent to the predicate devices Arthrex Continuous Wave III Arthroscopy Pump and the FMS DUO in which the basic features and intended uses are the same or very similar. Any differences between the Arthrex Dual Wave Arthroscopy Fluid Management Device and the predicate devices Arthrex Continuous Wave III Arthroscopy Pump and FMS DUO are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the new Arthrex Dual Wave Arthroscopy Fluid Management Device is substantially equivalent to the currently marketed predicate devices.

4 Administrative Information

4.1 Manufacturer / Distributor/ Sponsor / Contact

4.1.1 Manufacturer/Distributor / Sponsor

Arthrex, Inc.
1370 Creekside Boulevard
Naples, Florida 34108-1945 USA
Establishment Registration Number: 1220246

4.1.2 Contact

Sally Foust
Regulatory Affairs Project Manager
Arthrex, Inc.
1370 Creekside Boulevard
Naples, Florida 34108-1945 USA
Telephone: 239/643.5553, extension 1251
Fax: 239/598.5508
Email: sfoust@arthrex.com

4.2 Device Identification

4.2.1 Proprietary Name

Arthrex Dual Wave Arthroscopy Fluid Management System

4.2.2 Common Name

Pump

4.2.3 Classification Name and Reference

21 CFR 888.1111: Arthroscope

4.2.4 Regulatory Class

Based on the recommendation of the Orthopedic and Rehabilitation Device Panel, the FDA has classified this device as a Class II medical device.

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4.2.5 Device Product Code

- HRX

4.3 Compliance with Special Controls

Sections 513 and 514 of the act, as amended under the Safe Medical Devices Act of 1990, do apply to this type of device.

Arthrex, Inc. is not aware of any requirements for post-market surveillance or other special controls for this device.

4.4 Conformance to Voluntary Standards

The Arthrex Dual Wave Arthroscopy Fluid Management Device will conform to the following voluntary standards:

EN -55011B (EMC 89/336/CEE): Emission Requirements

IEC-60601-1 (73/23/CEE): Medical electrical equipment, General Requirements for Safety

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Arthrex, Inc.
% Ms. Sally Frost
Regulatory Affairs Project Manager
1370 Creekside Boulevard
Naples, Florida 34108

AUG 0 3 2009

Re: K083707
Trade/Device Name: Arthrex Dual Wave Arthroscopy Fluid Management Device
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: July 13, 2009
Received: July 15, 2009

Dear Ms. Forst:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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2 Indications for Use Form

Indications for Use

510(k) Number: _____

Device Name: **Arthrex Dual Wave Arthroscopy Fluid Management Device**

The Arthrex Dual Wave Arthroscopy Fluid Management Device is intended to provide consistent, non-pulsing control of intra-articular irrigation and distention pressuring during all phases of arthroscopic surgery.

Prescription Use _X_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K083707